

REMARKS

Claims 1 to 26 are pending in the application. No claims have been amended, canceled, or added, herein. Applicants respectfully request reconsideration of the rejections of record in view of the following remarks.

The Claimed Subject Matter Is Not Anticipated and Would Not Have Been Obvious

A. Claims 1 to 10 and 12 to 25 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or, alternatively, under 35 U.S.C. § 103(a) as allegedly obvious over, U.S. Patent No. 4,822,334 (“the Tapper patent”) or U.S. Patent No. 5,203,768 (“the Haak patent”). Applicants respectfully request reconsideration and withdrawal of the rejections because the Tapper and Haak patents, when considered individually or in combination, fail to teach or suggest every limitation of the present claims, and the Office has failed to establish that the missing limitations are inherent in the teachings of either patent.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

To establish *prima facie* obviousness, the Patent Office must demonstrate that the cited prior art reference or combination of references teaches or suggests *all* the limitations of the claims. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

The Tapper and Haak patents each fail to teach or suggest every limitation of the pending claims. Specifically, the patents each fail to teach or suggest electrotransport delivery devices, and methods of using the devices, in which a higher electrotransport agent delivery efficiency (E) state is induced in the body surface when the applied current density is greater than or equal to a critical current density level (I_c) and the applied pulsing current is applied for greater than or equal to a critical time period (t_c).

For example, the Tapper patent describes an iontophoretic method and apparatus for the delivery of medication to the human body in which the dosage of medication delivered is a product of the magnitude of the applied electrical current and the length of time that the

current is applied.¹ The patent does not suggest that enhanced electrotransport agent delivery efficiency can be achieved using the device if a current density greater than or equal to a critical current density is applied for greater than or equal to a critical time period. In fact, the patent teaches away from this concept by teaching that the magnitude of the current and the length of time that the current is delivered vary *inversely* during an administration procedure,² indicating that there is no lower limit at any time during a delivery procedure for both the magnitude of the current and the length of time that the current is applied. That is, the patent teaches that if the magnitude of the current is increased during an administration procedure, the length of time that the current is delivered is decreased, and *vice versa*.³ The patent fails to teach or suggest that both the magnitude of the current and length of time that the current is applied should not be below a certain level in order to achieve enhanced delivery efficiency.

Similarly, the Haak patent describes a transdermal drug delivery device that contains electrical circuitry for controlling the level of current produced by the device.⁴ The patent, however, does not teach or suggest that higher electrotransport agent delivery efficiency can be achieved using the device if the current density applied by the device is greater than or equal to a critical current density level and the pulsing current is applied for greater than or equal to a critical time period. The Tapper and Haak patents, when considered individually or in combination, thus fail to teach or suggest every limitation of the present claims.

Moreover, although the Office asserts that “values such as current and/or current density that are taught in Tapper to be ‘varied during an administration procedure’ will obviously if not inherently change the ‘properties’ of current to reflect Applicant’s claimed valued and/or ranges,”⁵ the Office has failed to provide the necessary showing that the limitations of the present claims that are not taught or suggested in the Tapper and Haak patents are inherent in the patents’ teachings. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

¹ Col. 2, lns 37 to 42 and col. 3, lns 18 to 21.

² Col. 5, lns 17 to 20.

³ *Id.*

⁴ Col. 10, lns. 44 to 45.

⁵ Office Action dated June 19, 2001, sentence bridging pages 4 to 5.

Inherency, however, may not be established by probabilities or possibilities. *The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*” *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-1951 (Fed. Cir. 1999) (emphasis added). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art.” *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The Office has failed to demonstrate that the electrotransport delivery devices described in the Tapper and Haak patents *necessarily* apply a current density greater than or equal to a critical current density *and necessarily* apply a pulsing current for greater than or equal to a critical time period, to induce a higher electrotransport agent delivery efficiency state. On the contrary, the Office merely *speculates* that the devices described in the Tapper and Haak patents *may* operate according to these parameters since the devices deliver a pulsing DC “that is certainly capable of being delivered at various current density levels for any period of time.”⁶ The Office has thus failed to establish that the Tapper and Haak patents inherently describe electrotransport delivery devices that achieve higher electrotransport agent delivery efficiency through application of a current density greater than or equal to a critical current density for greater than or equal to a critical period of time.

Since the Tapper and Haak patents, which considered individually or in combination, fail to explicitly or inherently teach or suggest every limitation recited in the present claims, the patents fail to anticipate and render the claimed subject matter obvious. Applicants accordingly, respectfully request withdrawal of the rejection.

B. Claims 3 to 6, 12, 13, 17 to 19, and 21 to 23 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over the Tapper patent in view of published PCT application number WO 91/15258 (“the Sorenson application”) and/or the Haak patent. Applicants respectfully request reconsideration and withdrawal of the rejection because the Office has failed to establish that the cited references teach or suggest all the limitations of the pending claims, and, hence, has failed to establish *prima facie* obviousness.

⁶ Office Action dated June 19, 2001, page 4.

As discussed above, the Tapper and Haak patents, when considered individually or in combination, fail to teach or suggest electrotransport delivery devices and methods of using the devices in which a higher electrotransport agent delivery efficiency (E) state is induced in a body surface when the applied current density is greater than or equal to a critical current density level (I_c) and the applied pulsing current is applied for greater than or equal to a critical time period (t_c). The Sorenson application does not compensate for the deficiencies of the Tapper and Haak patents. For example, the Sorenson application describes a two-stage iontophoretic drug delivery system in which iontophoretic current is delivered at a first level for a first predetermined interval of time to rapidly introduce a therapeutic agent into the bloodstream and the current is thereafter reduced to a second lower level to maintain a desired steady-state therapeutic level of the agent.⁷ The application fails to teach or suggest that a higher electrotransport agent delivery efficiency state is induced in the body surface if the applied current density is greater than or equal to a critical current density level and the applied pulsing current is applied for greater than or equal to a critical time period. The Tapper and Haak patents and the Sorenson application, when considered individually or in combination, thus fail to teach or suggest every limitation of the cited claims, and, hence, fail to render the claimed subject matter *prima facie* obvious. Applicants accordingly, respectfully request withdrawal of the rejection.

C. Claims 11 and 26 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over the Tapper patent in view of the Haak patent. Applicants respectfully request reconsideration and withdrawal of the rejection because the Office has failed to establish that the Tapper and Haak patents, when considered individually or in combination, teach or suggest electrotransport delivery devices and methods of using the devices in which a higher electrotransport agent delivery efficiency (E) state is induced in a body surface when the applied current density is greater than or equal to a critical current density level (I_c) and the applied pulsing current is applied for greater than or equal to a critical time period (t_c). The Office has, therefore, failed to establish *prima facie* obviousness, and Applicants accordingly, respectfully request withdrawal of the rejection.

⁷ Abstract.

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Information Disclosure Statements

As requested by the Examiner, Applicants acknowledge receipt of an initialed copy of the information disclosure statement that was filed with the Patent Office in connection with a request for continued examination on June 16, 2004. Applicants have still not received an initialed copy of the Form PTO 1449 that accompanied the information disclosure statement filed November 17, 1997, however, and Applicants respectfully ask the Examiner to return an initialed copy of that Form PTO 1449 to Applicants, confirming consideration of the listed references.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested.

Respectfully submitted,

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